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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,970	05/03/2006	Yukiko Sugihara	06303/HG	7540

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
12/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,970	SUGIHARA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-19 and 23-27* is/are pending in the application.

4a) Of the above claim(s) *9-18 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 29 Sep 2010, in which claims 23-26 are amended to change the scope and breadth of the claim and claims 20-22 are canceled.

This application is the national stage entry of PCT/JP04/17031, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-380194, filed 10 Nov 2003; currently an English language translation of this foreign priority document has not been made of record.

Claims 1-3, 6-19 and 23-27 are pending in the current application. Claims 9-18 and 27, drawn to non-elected inventions, are withdrawn. Claims 1-3, 6-8 and 19-26 are examined on the merits herein.

Objections Withdrawn

Applicant's Amendment, filed 29 Sep 2010, with respect to objections to claims 23-26 because a multiple dependent claim cannot depend from any other multiple dependent claim has been fully considered and is persuasive, as amended claims 23-26 are not multiple dependent claims dependent from any other multiple dependent claim.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 29 Sep 2010, with respect to claims 21 and 22 rejected under 35 U.S.C. 112, first paragraph as not being enabled for the full scope of the claim has been fully considered and is persuasive, as claims 21 and 22 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Sep 2010, with respect to claims 20 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record) has been fully considered and is persuasive, as claims 20 and 21 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Sep 2010, with respect to claims 20 and 21 provisionally rejected on the ground of nonstatutory double patenting over amended claims 1, 3, 5, 7 and 9-11 of copending Application No. 11/810524 has been fully considered and is persuasive, as claims 20 and 21 are canceled.

This provisional rejection has been **withdrawn**.

The following are new or modified grounds of rejection necessitated by Applicant's Amendment, filed 29 Sep 2010, in which claims 23-26 are amended to change the scope and breadth of the claim and claims 20-22 are canceled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record).

Inohara et al. discloses a composition containing a polysaccharide in water (abstract). Inohara et al. discloses a composition containing the 0.1 wt % of the polysaccharide agar in water (page 2, paragraph 26), meeting limitations of instant claims 23 and 24. Inohara et al. discloses the agar has a molecular weight preferably 30,000 to 800,000 (page 3, paragraph 30), meeting limitations of instant claim 25. Inohara et al. discloses said composition useful for application to an ocular mucous membrane in the form of a topically applied eyedrop with excellent characteristics (page 6, paragraph 62), implicitly meeting all structural limitations of the intended use of "stabilizing a tear film on an eyeball surface" of instant claims 23-25.

Response to Applicant's Remarks:

Applicant's Remarks, filed 29 Sep 2010, have been fully considered and not found to be persuasive with regard to the new grounds of rejection.

As detailed in the Office Action mailed 29 Jun 2010, claims 23-26 were not further treated on the merits as being a multiple dependent claim dependent from any other multiple dependent claim. Amended claims 23-26 are treated on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb

2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record) in view of Van Santivliet et al. (European Journal of Pharmaceutical Sciences, 1999, 7, p339-345, of record).

Inohara et al. discloses as above. Inohara et al. teaches the viscosity of said eyedrop measured using an E type viscometer may preferably be adjusted to 150 mPa*s or less (page 6, paragraph 66).

Inohara et al. does not specifically teach an agar-containing ophthalmic solution wherein a viscosity of the ophthalmic solution measured with an E type viscometer is 30 mPa*s or lower (instant claim 26).

Van Santivliet et al. teaches the level of skill in the art with regard to eyedrops as conventional dosage forms for ophthalmic formulations (page 339, abstract). Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s (page 339, right column, paragraph 1). Van Santivliet et al. teaches it is expected by one of ordinary skill in the art that for a given solution, increasing concentration of the viscolyser will increase the viscosity of the solution (page 343, table 3 at bottom of page), or conversely decreasing the concentration of the viscolyser will decrease the viscosity of the solution.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Inohara et al. in view of Van Santivliet et al. One of ordinary skill in the art would have been motivated to combine Inohara et al. in view of Van Santivliet et al. because Inohara et al. teaches an ophthalmic solution adjusted to 150 mPa*s or less and Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is

estimated at 15-30 mPa*s. One of ordinary skill in the art would have had a reasonable expectation of success to combine Inohara et al. in view of Van Santivliet et al. because Van Santivliet et al. teaches it is predictable to one of ordinary skill in the art that decreasing the concentration of the viscolyser will decrease the viscosity of the solution. It would have been obvious to one of ordinary skill in the art that the composition taught by Inohara et al. in view of Van Santivliet et al. would have implicitly met all structural limitations of the intended use of "stabilizing a tear film on an eyeball surface" because Inohara et al. discloses said composition useful for application to an ocular mucous membrane in the form of a topically applied eyedrop with excellent characteristics.

Response to Applicant's Remarks:

Applicant's Remarks, filed 29 Sep 2010, have been fully considered and not found to be persuasive with regard to the new grounds of rejection.

As detailed in the Office Action mailed 29 Jun 2010, claims 23-26 were not further treated on the merits as being a multiple dependent claim dependent from any other multiple dependent claim. Amended claims 23-26 are treated on the merits herein.

Amended Claims 1-3, 6-8 and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record) in view of Bourlais et al. (Progress in Retinal and Eye Research, 1998, 17(1), p33-58, of record)

and Van Santivliet et al. (European Journal of Pharmaceutical Sciences, 1999, 7, p339-345, of record).

Inohara et al. discloses as above. Inohara et al. teaches the viscosity of said eyedrop measured using an E type viscometer may preferably be adjusted to 150 mPa*s or less (page 6, paragraph 66).

Inohara et al. does not specifically teach the concentration of said polysaccharide is 0.0001 to 0.01 wt% and the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour (instant claim 1). Inohara et al. does not specifically disclose the composition being operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal (instant claim 6) and wherein the mucous membrane is an ocular mucous membrane (instant claim 7). Inohara et al. does not specifically teach the composition as a contact lens-wearing solution or a contact lens preservative solution (instant claim 19). Inohara et al. does not specifically teach the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000 xg for one hour and the composition being characterized by uniformly dispersing on an ocular surface when administered in the eye (instant claim 22). Inohara et al. does not specifically teach an agar-containing ophthalmic solution wherein a viscosity of the ophthalmic solution measured with an E type viscometer is 30 mPa*s or lower (instant claim 26).

Bourlais et al. teaches the level of skill in the art with regard to eyedrops as conventional dosage forms for ophthalmic formulations (page 34, abstract). Bourlais et al. teaches eyedrops made of polymeric gels are known in the art (page 36, section 2.

POLYMERIC GELS at right column). Bourlais et al. teaches highly viscous solutions of bioadhesive hydrogels are often associated with discomfort and result in blurred vision (page 40, right column, paragraph 2 and page 41, left column, paragraph 1).

Van Santivliet et al. teaches the level of skill in the art with regard to eyedrops as conventional dosage forms for ophthalmic formulations (page 339, abstract). Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s (page 339, right column, paragraph 1). Van Santivliet et al. teaches that it is expected to one of ordinary skill in the art that for a given solution, increasing concentration of the viscolyser will increase the viscosity of the solution (page 343, table 3 at bottom of page), or conversely decreasing the concentration of the viscolyser will decrease the viscosity of the solution.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. All of Inohara et al., Bourlais et al. and Van Santivliet et al. are drawn to eyedrops as conventional dosage forms for ophthalmic formulations. One of ordinary skill in the art would have been motivated to combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. in order to optimize the concentration of said polysaccharide to be 0.0001 to 0.01 wt% because Inohara et al. teaches the viscosity of said eyedrop may preferably be adjusted to 150 mPa*s or less, Bourlais et al. teaches highly viscous solutions of bioadhesive hydrogels are often associated undesirable side effects, and Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s. One of ordinary skill in the art would have had a reasonable expectation

of success in combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. because Van Santivliet et al. teaches that it is expected to one of ordinary skill in the art that for a given solution decreasing concentration of the viscolyser will decrease the viscosity of the solution. It would have been obvious to one of ordinary skill in the art that the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour would have been less than 65 wt%, 55 wt% or 30 wt% because the invention of Inohara et al. teaches agar obtained in the state of a liquid composition not in the state of a gel (page 2, paragraph 26) having a low viscosity during storage (page 3, paragraph 36) and giving a liquid composition without gelling (page 4, paragraph 48 and page 7, paragraph 73). It would have been obvious to one of ordinary skill in the art that the composition taught by Inohara et al. in view of Bourlais et al. and Van Santivliet et al. teaches all structural limitations of the composition capable of performing the intended use of being "operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal" and "wherein the mucous membrane is an ocular mucous membrane" of instant claims 6 and 7.

Response to Applicant's Remarks:

Applicant's Remarks, filed 29 Sep 2010, have been fully considered and not found to be persuasive.

As detailed in the Office Action mailed 29 Jun 2010, claims 23-26 were not further treated on the merits as being a multiple dependent claim dependent from any other multiple dependent claim. Amended claims 23-26 are treated on the merits herein.

Applicant notes that the comparative examples 3 and 4 of the instant specification correspond to embodiments of Inohara et al. WIPO Publication WO 2003/013612, in which a significantly high ratio of agar is precipitated compared to the instant invention. However, Inohara et al. teaches the agar dissolved "perfectly" into liquid in contrast to having partially dissolved particles (page 6, paragraph 67) and suggests it is desirable to avoid gelling (page 7, paragraph 69). Inohara et al. teaches increasing in agar content results in high viscosity and gelling in some cases (page 6, paragraph 65). Bourlais et al. teaches it is desirable to avoid highly viscous solutions of ophthalmic formulations because they are often associated with discomfort and result in blurred vision. Van Santivliet et al. teaches that it is expected to one of ordinary skill in the art that for a given solution decreasing the concentration of the viscolyser will decrease the viscosity of the solution and the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s. In view of the combined teaching of Inohara et al. in view of Bourlais et al. and Van Santivliet et al., one of ordinary skill in the art would have been motivated to reduce the concentration of agar in the invention taught by Inohara et al. and would have predicted a reduction in gelling and partially dissolved particles, or precipitated agar, as a result of decreasing the concentration of agar in order to decrease the viscosity of the ophthalmic solution. One of ordinary skill in the art would have predicted a significant tear film stabilizing effect because Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s. Therefore, in view of the combined teaching of Inohara et al. in view of Bourlais et al. and Van Santivliet et al. one of ordinary skill in the art would have been motivated to

combine the teachings to give a composition having properties that are predictable with a reasonable expectation of success.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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